K122011

510 (K) SUMMARY FOR BRAINLAB HIP

Manufacturer:	Brainlab AG Kapellenstrasse 12 85622 Feldkirchen Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 33
Submitter:	Rainer Birkenbach
Contact Person:	Alexander Schwiersch
Summary Date:	10/17/2012
Device:	Brainlab Hip
Trade Name:	Navigation Software Hip - Universal Navigation Software Hip THR – Aesculap Navigation Software Hip THR - Biomet US Navigation Software Hip THR - DePuy US Navigation Software Hip THR - Smith&Nephew US Navigation Software Hip THR – Zimmer Navigation Software Hip Express Navigation Software Hip SR Universal Navigation Software Hip SR - Biomet US Navigation Software Hip SR - Corin US Navigation Software Hip SR - Wright Medical Navigation Software Hip SR – Zimmer Navigation Package Hip Unlimited US
Common/Classification Name:	Brainlab Hip, Brainlab Image Guided Surgery System / Instrument, Stereotaxic
Predicate Device:	BrainLAB hip unlimited (K083483) Vector Vision® hip SR (K063028) DASH hip (K110021) Brainlab Knee (K102990) Brainlab Trauma (K110204)
Device Classification Name:	Instrument, Stereotaxic
Regulatory Class:	Class II
Regulation Number:	21 CFR 882.4560
Product Code:	OLO / HAW
Intended Use:	**For Total Hip Replacement (THR) procedures** The Brainlab hip system is intended to be an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system, to virtual computer image space either on a patient's preoperative image data being processed by Brainlab IGS platforms, or on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks

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on the bone surface.

The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-Ray, or MR-based model of the anatomy. The system aids the surgeon to accurately navigate a hip endoprosthesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

Total Joint Replacement

Minimally invasive orthopedic surgery

Tumor resection and bone/joint reconstruction

For Surface Replacement (SR) procedures

The Brainlab hip system is intended as an intraoperative image-guided localization system. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on Brainlab IGS platforms. The image data is provided either in the form of preoperatively-acquired patient images or in the form of an individual 3D model of the patient's bone, which is generated by acquiring multiple landmarks on the bone surface.

The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, or MR-based model of the anatomy. The system aids the surgeon in accurately navigating a hip endoprothesis to the preoperatively or intraoperatively planned position.

Example orthopedic surgical procedures include but are not limited to:

Partial/hemi-hip resurfacing

Device Description:

The Brainlab hip system is intended to enable operational planning and navigation in orthopedic hip replacement surgery. It links a surgical instrument, tracked by passive markers to virtual computer image space on an individual three-dimensional model of the patient's bone, which is generated through acquiring multiple landmarks either directly on the bone surface or by palpating bony landmarks through soft tissue and defining them directly on skin. The Brainlab hip system uses the registered landmarks to navigate the necessary surgical tools, e.g., cup reamer, cup inserter, stem broach handles and k-wires, to the planned position and orientation. Additionally, it enables to intra-operative measurement of implant position, including measurement of the changes in leg length and offset.

The Brainlab hip system provides a three-dimensional reconstruction of the relevant anatomical axes and planes of the femur and pelvis to aid the alignment of the implants and to determine leg length and offset parameters. Based on the selected procedure, the Brainlab hip system loads implant and instrument data that has been provided by the implant manufacturer. It is possible to individually choose the prostheses for each surgery, which are shown in the software in relation to the determined anatomical structures. If no implant data is available, to the user can enter

information in order to achieve a generally targeted alignment. The Brainlab hip system does not require CT-based imaging.

Substantial Equivalence:

Brainlab hip system has been verified and validated according to Brainlab's procedures for product design and development. The information provided by Brainlab in this 510 (k) application was found to be substantially equivalent with the predicate devices:

- BrainLAB hip unlimited (K083483)
- Vector Vision® hip SR (K063028)
- DASH hip (K110021)
- Brainlab Knee (K102990)
- Brainlab Trauma (K110204)

Changes to Predicate Device:

Brainlab Hip has changed in the following from the predicate devices:

- Elements of the user interface and workflows have been redesigned to reduce the user interaction with the system and enable a faster run through the registration and navigation procedures.
- Modified registration techniques have been integrated which reduce the number of landmarks to be acquired. For the pelvis, an indirect reconstruction of the anterior pelvic plane can be performed based on a reduced set of landmarks. Information about pelvic tilt can be used to adapt the cup orientation, e.g., to a coronal plane when the patient is standing upright.
- A distance measurement tool has been integrated which allows to check how well seated a cup implant is on the acetabular floor during cup insertion.
- For hip surface replacement procedures, a method for the verification of the head implant has been integrated.
- New implants and instruments have been integrated (including a new pointer device, a caliper to measure anatomical relationships of the pelvis, and new data of FDA-cleared implants provided by the implant manufacturers).

All modifications of the new device are covered by the indications for use of new and predicate devices and are only minor changes, as the basic technology has not changed.

Technological Characteristics:

The literature research and the comparison to the predicate devices show that the device makes use of equivalent technological characteristics and functionality and is intended for equivalent surgical procedures as compared to the predicate devices.

Non-clinical Performance Data

The following non-clinical tests have been performed to ensure correct system functionality according to its specifications:

- Specific test objectives have been used to show the correctness of new features in the Brainlab hip system.
- A detailed verification of the signed specifications was performed covering the detailed functionality of the software (e.g. workflows, GUI elements, usage of instruments).
- The measures have been tested against the defined risks of the Risk Analysis.
- Literature research has been performed to ensure that Brainlab hip conforms to user needs and intended uses as well.
- Non-clinical tests were performed to confirm the system targets. Specific OR setups and surgical procedures were simulated in laboratory environments and cadaver labs.

Clinical Performance Data

A prospective clinical validation study was performed to analyze the accuracy of lateral and supine pelvis registration in Brainlab Hip. The study included 50 total hip replacement surgeries on patients over 55 years of age. Patients with previous ipsilateral hip surgery affecting the pelvic or acetabular anatomy, pelvic fracture, ipsilateral acetabular fracture and women with childbearing potential were excluded. Two patients had to be excluded because of a loss of the navigation data (one case) and loosening of the pelvic reference array (one case). No intra- or post-operative complications occurred in the remaining cases except one calcar fissure which was unrelated to the navigation and caused no post-operative problems.

The surgical procedure was performed using the previous version of Brainlab Hip, the Brainlab Hip 5.1 navigation system, including an epicutaneous acquisition of the anterior pelvis plane (APP) as the basic reference for intraoperative navigation. This reflects an established registration procedure. The final position of the cup was verified based on this registration. Additionally, all landmarks required for Brainlab Hip registration procedures were acquired. Based on this information, the verified cup orientation was virtually adapted to the registration methods of Brainlab Hip. Post-operative CT scans were performed to determine a gold standard registration by defining the APP points directly on bone. Cup orientation was measured for this reference and then compared to the virtually adapted cup orientation. This enabled a direct comparison of the lateral and supine registration methods in Brainlab Hip with the gold standard.

The descriptive statistics (mean ± standard deviation) of the deviations to the gold standard, as well as the percentage of cases within a ±10° safe zone, as defined by Lewinnek et al in *Lewinnek GE, Lewis JL, Tarr R, Compere CL, Zimmerman JR. Dislocations after total hip-replacement arthroplasties. J Bone Joint Surg Am. 1978 Mar;60(2):217-20,* were calculated according to the radiographic definition specified by Murray DW in *The definition and measurement of acetabular orientation. J Bone Joint Surg Br. 1993 Mar; 75(2): 228-32.* The percentages were calculated based on the actual numbers of cases, as well as a statistical calculation where error distribution was modeled as a normal distribution.

- Deviation between gold standard and Brainlab Hip lateral registration:
  - Inclination: -1.1° ± 3.1°, statistically 0.25% of the cases were

outside the ±10° safe zone

- Anteversion: 0.9° ± 4.3°, statistically 2.32% of the cases were outside the ±10° safe zone

- Deviation between gold standard and Brainlab Hip supine registration:
  - Inclination: 0.5° ± 2.2°, statistically 0.0% of the cases were outside the ±10° safe zone
  - Anteversion: -0.9° ± 3.9°, statistically 1.2% of the cases were outside the ±10° safe zone

The deviation was not outside the safe zone in any of the actual cases. This was true for both lateral and supine registration methods. These results describe the basic accuracy of cup orientation measurement in Brainlab Hip.

Conclusion

All non-clinical and clinical tests have been successfully performed. Thus, it has been demonstrated that the device is as safe, as effective, and performs as well as the predicate device.

(Division Sign-Off)
Division of Surgical Orthopedic, and Restorative Devices

510(k) Number K112011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Brainlab AG
% Mr. Alexander Schwiersch
Regulatory Affairs Manager
Kapellenstrasse 12
Feldkirchen, Germany 85622

November 15, 2012

Re: K122011
Trade/Device Name: Brainlab Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO
Dated: October 24, 2012
Received: October 26, 2012

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K122011

Device name: Brainlab Hip

Indication for use:

Total Hip Replacement (THR) procedures

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Partial/hemi-hip resurfacing.

Prescription Use _____X_____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices
Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K122011